REMARKS

Claims 1-147 are pending in the application prior to entry of amendments submitted herewith. Claims 45-147 are withdrawn from consideration. Claims 1-44 have been examined and all of those Claims stand rejected. By amendment herewith, Claims 1, 4-7, 9-31 and 33-44 are being changed and Claims 2, 3, 8, 32 and 45-147 are being cancelled herewith.

I. Rejection Under 35 U.S.C. § 112, Second Paragraph.

The Examiner has rejected claims 1-44 under 35 U.S.C. § 112, second paragraph, asserting indefiniteness for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 1, the Examiner has specifically objected to "an immunogen composition", "a biocompatible polymer" and "a liquid vehicle" as not being defined. These claims are clear and not indefinite, but the terms have been removed from the claim in an effort to accommodate the Examiner's textual preferences, and not for any reason related to patentability. It is noted that the word "biocompatible" has been retained in Claim 1 in a definitional context consistent with that provided at page 13, lines 11-12 of the specification.

In Claim 1, the Examiner also objected to the term "at least" as being a relative term. However, there is no prohibition in the patent laws to using a relative term, and terms are not indefinite simply because they are relative. For example, MPEP § 2173.05(c), part II, specifically notes an example using the term "at least" and indicates that the term is acceptable unless its use in one claim is inconsistent with the limitations of another claim. Moreover, the Examiner's position is unsupported by the case law. In one case, the Federal Circuit Court of Appeals found that a limitation of "at least two" in a claim "sets forth a minimum number of a particular element required." *Lantech, Inc. v. Keip Mach. Co.*, 32 F.3d 542, 546, 31 U.S.P.Q.2d 1666 (Fed. Cir. 1994). Likewise, in another case, the Federal Circuit Court of Appeals noted that the term "at least" in a claim means "as the minimum," citing to Webster's Third New International Dictionary 1287 (1986). *Quantum Corp. v. Rodime*, 65 F.3d 1577,1581, 36 U.S.P.Q.2d 1162 (Fed. Cir. 1995). In the Quantum case, the Federal Circuit affirmed the District Court's interpretation that a claim limitation that a hard-disk track density is "at least 600 tpi" has an ordinary meaning that "indicates densities starting at, but greater than 600 tpi." *Quantum*, at

65 F.3d 1580. Copies of these and other cases cited herein are enclosed for the Examiner's convenience. The Examiner's objection that "at least" is indefinite because it is a relative term is not correct. Nevertheless, the term "at least" has been removed from Claim 1 in an effort to accommodate the Examiner's textual preferences, and not for any reason related to patentability.

In Claim 2, the Examiner has objected to limitation of a temperature below 40 °C. The claim has been cancelled, mooting the objection, even though there is no prohibition against claiming open-ended ranges, as seems to be the Examiner's position.

In Claim 4 the Examiner has objected to the limitation "at least", again on the asserted basis that it is a relative word and therefore indefinite. As noted above, this assertion is not correct, but the term has been removed from the claim in an effort to accommodate the Examiner's textual preferences, and not for any reason related to patentability.

In Claims 15, 20, 21, 23 and 24, the Examiner has objected to the term "derived". Even though the term is clear and not indefinite, the term has been removed from the claim in an effort to accommodate the Examiner's textual preferences, and not for any reason related to patentability.

In Claims 15-30, the Examiner has objected to the term "at least," again for the asserted reason that the term is indefinite simply because it is a relative term. Even though the assertion is not correct, the term has been removed from the claim in an effort to accommodate the Examiner's textual preferences, and not for any reason related to patentability.

In Claim 32, the Examiner has objected to "the metes and bounds of products of microorganisms" not being defined and to use of the term "such as". The claim has been cancelled, rendering the objections moot.

II. Rejection Under 35 U.S.C. § 112, First Paragraph.

The Examiner rejected Claims 1-44 under 35 U.S.C. § 112, first paragraph, as not being enabled for "using any polymer plus any adjuvants to get an enhanced immune response with any or all antigens." The rejection is traversed.

For enablement, the Examiner appears to require a working example for each claimed combination demonstrating that the use of each claimed combination would produce an enhanced immune response. The Examiner's analysis with respect to enablement is not correct. Enablement does not require that a working example be provided for every combination or that

every combination when used would provide an "enhanced immune response." This becomes especially clear when considering the nature of this invention and the level of information and guidance provided in the specification concerning how to make and use the claimed composition.

The specification provides significant information and guidance on selection and formulation of the antigen, polymer, adjuvant and liquid components to make the claimed composition, and also concerning use of the composition, including administration routes. Exemplary antigens and concentrations of antigens for use in the composition are described in the specification, *inter alia*, at page 14, line 14 through page 15, line 22. Exemplary polymers and concentrations of polymers for use in the composition are described in the specification, *inter alia*, at page 16, line12 through page 19, line 19. Exemplary adjuvants and concentrations of adjuvants or use in the composition are described in the specification, *inter alia*, at page 20 lines 7-29. The liquid and preparation of the composition is described in the specification, *inter alia*, at page 21, lines 1-22. Use of the composition, including exemplary administration routes, is described in the specification, *inter alia*, at page 22, line 6 through page 24, line 7. This significant information and guidance concerning making and using the claimed composition cannot be ignored in assessing enablement.

In addition to the significant information and guidance noted above, the specification also presents numerous working examples at pages 25-34 of the specification. In these working examples, tests are presented involving tetanus toxoid, chicken ovalbumin and diphtheria toxoid formulated with Pluronic® F127 polymer and chitosan. The specific working examples presented on pages 25-33 supplement the descriptions of the invention presented in other parts of the specification, and do not limit the scope of the invention but do aid understanding of the invention. The presentation of working examples may contribute to the enabling character of the disclosure, but as is clearly stated in MPEP § 2164.02, "Compliance with the enablement requirement of 35 U.S.C. 112 , first paragraph, does not turn on whether an example is disclosed." [Emphasis added.]

The Examiner asserts that the field "is unpredictable because different antigens have different characteristics and behave differently," and that evidence is not provided "to support that any or all antigen formulated with any or all copolymer . . . in combination with any or all adjuvants . . . is able to induce an enhanced immune response in vivo." The Examiner then summarily concludes, that "undue experimentation would be required to enable the intended

claim." The nature of the invention, however, does not involve development of new antigens, adjuvants, polymers or other chemicals. Rather, the invention of Claims 1-44 involves formulation of antigens for delivery, with the formulation including an adjuvant and a polymer/liquid combination that imparts a reverse thermal viscosity behavior to the composition.

35 U.S.C. § 112, first paragraph, requires only that one of ordinary skill in the art be enabled to make and use the invention, and the **invention is defined by the claims**. *See*, first paragraph of MPEP 2164. The present invention should not be unduly restricted relative to the nature of the invention as a combination of components that are not themselves the subject of development. In that regard, reference is made to the case of *In Re Fuetterrer*, 319 F.2d 259, 138 USPQ 217 (CCPA 1963), a copy of which is enclosed. In *Fueterrer*, the claims at issue recited a rubber stock for producing tire treads including "a mixture of a non-adhesive protein and a carbohydrate which mixture is substantially insoluble in cold water" and including an "inorganic salt that is capable of holding a mixture of said carbohydrate and protein in colloidal suspension in water." *Fuetterrer*, at 319 F.2d 260. The Patent Office rejected the claims, and the Patent Office Board of Appeals affirmed the rejection on grounds that the claims were too broadly drawn because only four of the large number of possible inorganic salts were disclosed in the application. The CCPA overturned the rejection stating that the specification need not set forth all salts which could operate in the claimed combination. The court in *Fuetterrer* rejected the Patent Office's assertion that identifying usable salts would involve undue experimentation and specifically stated:

> Applicant's invention is the *combination* claimed and not the discovery that certain inorganic salts have colloidal suspending properties. We see nothing in the patent law which requires applicant to discover which of all those salts have such properties and which will function properly in his combination. The invention description clearly indicates that any organic salt which has such properties is usable in his combination. If others in the future discover that inorganic salts additional to those enumerated do have such properties, it is clear applicant will have no control over them per se, and equally clear his claims should not be so restricted that they can be avoided merely by using some inorganic salt not named by applicant in his disclosure. The only "undue burden" which is apparent to us in the instant case is that which the patent office has attempted to place on the applicant. The patent office would require him to do research on "literally thousands" of inorganic salts and determine which of these are suitable for incorporation into his claimed combination, apparently forgetting that he has not invented, and is not

claiming colloidal suspending agents but tire tread stock composed of a combination of rubber and other ingredients. [*Fueterrer*, at 319 F.2d 265, emphasis as in original.]

Likewise, the instant invention of Claims 1-44 is not premised on the discovery of new antigens, polymers or adjuvants. Rather, the claimed composition involves a specific recited combination of antigen, adjuvant, polymer and liquid components in an antigen delivery formulation having reverse thermal viscosification behavior. Consistent with the holding of the CCPA in Fueterrer, claims to the present invention should not be unduly restricted in a manner to permit others to easily circumvent the claims simply because the applicant has not identified every specific combination of antigen, polymer, adjuvant and liquid or provided a working example for each such possible combination. Again, the claims are not directed to new antigens, adjuvants or polymers, per se, but rather only to a specific combination of those materials for delivery of the antigen.

Moreover, there is no requirement for enablement that each and every possible combination within the claims be demonstrated to provide an "enhanced" performance, as suggested by the Examiner. There is no enablement requirement that claims must be limited to covering only preferred embodiments, or that each claimed embodiment must necessarily be demonstrated to provide some "enhanced" level of performance. The specification provides significant guidance on exemplary antigens, adjuvants, polymers and liquids that may be used as components to make the combination of the claimed composition, how those components may be combined to make the composition having the reverse thermal viscosification behavior, and how the prepared composition may be administered by a variety of routes for delivery of the antigen. It would be a simple matter for one of ordinary skill in the art considering any specific antigen, adjuvant, polymer and liquid combination to simply prepare a sample formulation of the combination and test it for the presence of the reverse thermal viscosification behavior. Such experimentation could hardly be considered undue.

The Examiner is respectfully requested to withdraw the rejection under 35 U.S.C. § 112, first paragraph.

III. Rejection under Obviousness-Type Double Patenting.

Claims 1-32, 34-37 and 44 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting with respect to identified of claims of Application No. 09/602,654. Application No. 09/602,654 is now abandoned, rendering the provisional rejection moot. The provisional rejection should be withdrawn.

IV. Rejections under 35 U.S.C. §§102(b) and (e).

The Examiner has rejected Claims 1-32, and 38-44 as being anticipated under 35 U.S.C. § 102(e) by Balasubramanian et al. (U.S. Patent No. 6,086,899, referred to herein as "Balasubramanian '899"), Claims 1-31 and 43-44 as being anticipated under 35 U.S.C. §102(b) by Ron et al. (WO 98/06438A2, referred to herein as "Ron") and Claims 1-31, 34 and 38-44 under 35 U.S.C. §102(e) by Balasubramanian et al. (U.S. Patent No. 6,416,947, referred to herein as "Balasubramanian '947"). The rejections are traversed.

Independent Claim 1 is directed to a composition for delivery of an antigen, the composition requiring a specific combination of at least four specified components combined in a manner to provide specific formulation properties, namely the composition of Claim 1 requires an antigen, a polyoxyalkylene block copolymer that is biocompatible, an adjuvant other than alum, and a liquid, with the copolymer and the liquid in the formulation interacting to impart specific reverse thermal viscosity behavior to the composition so that viscosity of the composition increases over some range of temperatures falling between 1 °C and 37 °C. As discussed in the application, the conventional use of alum in vaccine compositions has certain drawbacks. The composition of the present invention as set forth in Claim 1 specifically requires the use of an adjuvant other than alum. Although alum may be present in the claimed composition of the invention in addition to the specified non-alum adjuvant, as discussed in the specification in one preferred embodiment the composition does not contain any alum.

Balasubramanian '899 and Balasubramanian '947 share a common priority and have similar disclosures, and each discloses a specific high molecular weight polyoxyethylene/polyoxypropylene block copolymer and use of the block copolymer in relation to delivery of antigens. These references each describe the new copolymers as being particularly useful as surfactants and as adjuvants in vaccines. *See*, Balasubramanian '947 in the abstract; at column 3, lines 14-25; at column 8, lines 43-45; and at column 9, lines 4-46. *See*, Balasubramanian '899 in the abstract; at column 3 at lines 11-22; at column 8, lines 40-42; and at

column 9, lines 1-39. For both Balasubramanian references, therefore, the novel copolymer is disclosed for use as a surfactant and adjuvant.

Conversely, the composition of Claim 1 requires that there be a polyoxyalkylene block copolymer and a separate specified adjuvant that is different than the polyoxyalkylene block copolymer. Whereas Balasubramanian '899 and '947 appear to be directed to a new adjuvant, in the form of the novel copolymer, and use of that new adjuvant, the present invention as recited in Claim 1 is not directed to development of new adjuvants, but to formulating adjuvants, that may now exist or later be discovered, with antigens and a specified polymer in a delivery composition exhibiting reverse-thermal viscosification behavior.

The disclosures of Balasubramanian '899 and '947 do not disclose vaccine formulations with reverse-thermal viscosity behavior, or even that the novel copolymer would be useful to impart such reverse-thermal viscosity behavior. The Examiner does refer to each of the Balasubramanian references as disclosing "Qui-A sopanin, etc." A review of the Balasubramanian references reveals that in Examples V and VII of each of Balasubramanian '899 and '947, comparison formulations with Qui-A sopanin, or with other comparison adjuvants, were tested relative to formulations including the novel copolymer adjuvant of the Balasubramanian references, to compare performance of the novel copolymer adjuvant with the comparison adjuvants. But there is no disclosure or suggestion in Balasubrananian '899 or '947 of the composition of Claim 1, which requires formulation of an antigen and a non-alum adjuvant together with a polyoxyalkylene block copolymer and liquid formulated with reverse-thermal viscosity behavior.

Ron discloses a novel reversibly gelling polymer network and use of the reversibly gelling polymer network for pharmaceutical delivery applications. (*See*, Ron, *inter alia*, at page 4, line 28 through page 8, line 4). In a broad-brush identification of possible applications and possible pharmaceuticals for use with the novel polymer network, at page 31, lines 6-21, Ron gives passing reference to possible use of the novel polymer network with some antigens. The broad-brush disclosure by Ron for potential applications and pharmaceuticals for use with the novel polymer network of Ron does not disclose or suggest the very specific combination of elements in the composition for antigen delivery as recited in Claim 1, which again requires formulation of an antigen and a non-alum adjuvant together with a polyoxyalkylene block copolymer and liquid with reverse-thermal viscosity behavior. No discussion could be found in

Ron of formulating antigens with non-alum adjuvants, let alone in the precise combination claimed with the present invention.

Based on the foregoing, the Examiner should withdraw the rejections under 35 U.S.C. §§ 102(b) and 102(e).

V. Rejections Under 35 U.S.C. §103(a).

The Examiner has rejected Claims 1-44 under 35 U.S.C. § 103(a) citing to a total of six allegedly combinable references: (1) Balasubramanian '947, (2) Viegas et al. (U.S. Patent No. 5,071,644; referred to herein as "Viegas '644"), (3) Viegas et al. (U.S. Patent No. 5,593,683; referred to herein as "Viegas '683"), (4) Illum et al. (Pharmaceutical Research, 1994, Vol. 11, No. 1186-1189; referred to herein as "Illum"), (5) Cox (Vaccine 1997, Vol. 15, pp. 248-256; referred to herein as "Cox"), and (6) Horner et al. (Cellular Immunology 1998, Vol. 190, pp. 77-82; referred to herein as "Horner"). The Examiner has also rejected Claims 1-44 under 35 U.S.C. § 103(a) citing to another group of four allegedly combinable references: (1) Ron, (2) Illum, (3) Cox and (4) Horner. These rejections are traversed.

With respect to each rejection under 35 U.S.C §103(a), the analysis presented in the Office Action appears to pick and choose claimed elements from a number of references and then, apparently using hindsight with the invention as a guide, to find obvious the combination of those elements in the precise manner of the invention. Such an approach is not proper. Rather, there must be some suggestion or motivation provided by the references for making the specific combination.

With respect to Balasubramanian '947 et al., the Examiner specifically notes, consistent with the discussion above concerning 35 U.S.C. § 102(e), that the reference does not teach all of the limitations of Claims 1-44. The Examiner specifically notes deficiencies in Balasubramanian '947 with respect to the reverse-thermal viscosity and adjuvant limitations of the Claims. As discussed above, Balasumbramian '947 does not disclose the specific combination of elements of the invention of Claims 1-44.

Failing to identify the reverse-thermal viscosity and adjuvant limitations in Balasubramanian '947, the Examiner then cites to Viegas '644 and Viegas '683, apparently as supplying the reverse-thermal viscosity limitation. Even though the two Viegas references have considerably different disclosures, the Examiner cites them together as disclosing certain

polyoxyethylene/polyoxypropylene polymers that can be delivered in an aqueous mixture as a low viscosity liquid at ambient temperature that, upon contact with the mammalian body, forms a semi-solid gel having a very high viscosity. The Office Action, however, provides no discussion concerning any motivations or suggestions in Balasubramanian '947 or the Viegas patents that would motivate combination of the teachings of those references for purposes of 35 U.S.C. § 103(a) analysis to render obvious the specific claimed combination. A review of the references reveals no such suggestions or motivations. For example, Balasubramanian '947 is focused on a novel polyoxyethylene/polyoxypropylene block copolymer and certain compositions including the novel polymer for vaccine delivery. Balasubramanian "947 specifically identifies problems with prior art polyoxyethylene/polyoxypropylene block copolymers (which would include the prior polymers of the Viegas patents) and distinguishes the novel polymer of Balasubramanian from those prior art polymers. *See*, Balasubramanian '947 at column 1, line 63 through column 2, line 13 and at column 2, line 66 through column 3, line 10 concerning problems with prior art polyoxyethylene/polyoxypropylene block copolymers and a need for new polymers; and at column 3, lines 14-25 concerning distinguishing the novel polymer based on a higher molecular weight hydrophobic region. Where is the suggestion or motivation to look to the Viegas patents to identify different polymers to replace the specific polymers that Balasubramanian has indicated are designed especially for vaccine delivery and to provide adjuvant properties? The very focus of Balasubramanian '947 is to address identified problems with other polyoxyethylene/polyoxypropylene block copolymers, and it would be counterintuitive to combine the teachings of Balasubramanian '947 with the teachings of the Viegas patents, because Balasubamanian '947 is a teaching away from the polymers of the Viegas patents. Moreover, neither of the Viegas patents even mentions delivery of antigens. Even between the Viegas patents there is no uniform presentation concerning polymer functionality. For example, Viegas '644 specifically discusses thermo-irreversible gel compositions and Viegas '683 discusses thermoreversible gel compositions, and each patent concerns different pharmaceutical applications.

The Examiner cites to the technical papers of Illum, Cox and Horner as providing disclosure concerning adjuvants. Again, Balasubramanian '947 specifically focuses on providing novel polyoxyethylene/polyoxypropylene block copolymer that itself is an adjuvant for antigens, and Balasubramanian '947 goes to considerable effort to present examples distinguishing the

adjuvant properties of the novel copolymer from the properties of other adjuvants. Balasubramanian '947 is specifically distinguishing the novel copolymer as an antigen adjuvant, and it would be counterintuitive to combine the teachings of Balasubramanian '947 with the teachings of the any of Illum, Cox and Horner, because Balssubamanian is a teaching away from the use of other adjuvants.

With respect to Ron, as discussed above, the reference discusses a pharmaceutic composition with a key component being a carrier comprising a novel reverse thermally viscosifying polymer network that includes a responsive polymer component bonded to a structural component. In broad-brush fashion, Ron proposes use of the carrier for potential delivery of a vast number of pharmaceuticals, including antigens. There is no suggestion or motivation provided by Ron for modification of the compositions of Ron et al. to focus on antigen delivery, let alone on the specific combination of components of the invention of Claims 1-44 to effect antigen delivery. Moreover, none of Illum, Cox or Horner provide any such suggestion or motivation to arrive at the specific combination of the invention of Claims 1-44, similar to the discussion above with respect to those references in relation to potential combination with Balasubramanian '947.

The Examiner's approach of selectively extracting individual elements from the context of the various references and combining those elements in a different context to make the specific combination of the invention is not proper. None of the references cited by the Examiner contains any suggestion or provides any motivation for making the combination. The common trait among the references cited by the Examiner is that they all deal with drug delivery, with some of them particularly discussing antigen delivery.

Again, it is emphasized that the nature of the invention of Claims 1-44 is not the discovery of new antigens, new polymers, or new adjuvants, but is rather a very specific and narrow combination of components and formulation properties for an antigen delivery composition. There may be thousands of materials and formulations of materials that have been used or described for use in one form or another in relation to delivery of antigens, but the examiner has made no showing of why one of ordinary skill in the art would select the specific components recited in Claims 1-44 and then combine those specific components in the specific and narrow combination of Claims 1-44. It is no more proper to pick and choose among and combine the multitude of materials that may have been disclosed in relation to drug delivery to

assert the obviousness of the combination of the claimed composition of the invention than it is to pick and choose among and combine mechanical components from a hardware store to assert that a new mechanical structure is obvious. There must be some suggestion in the prior art that would lead to the specific claimed combination.

Moreover, information presented in the examples at pages 25-33 further distinguishes the composition of the invention. In the examples, mice studies involving tetanus toxoid, diphtheria toxoid and chicken ovalbumin are summarized. The results presented in the examples indicate a significantly enhanced performance in tests using compositions of the invention including the antigen and both F127 polymer and chitosan relative to comparable tests using comparison compositions including the antigen with only chitosan (and not F127 polymer) or the antigen without either chitosan or F127 polymer. Particular attention is drawn to test results indicating a significantly enhanced response at early times following administration. Obtaining an enhanced early immunization response may be critical to survival in an epidemic or other high risk situation. In that regard, reference is made specifically to Examples 5 and 7 in the specification.

In Example 5 in the specification, different groups of Balb/c mice are given a prime administration intraperitoneally of 1.5 Lf tetanus toxoid (TT) and then 4 weeks later are given a boost administration intranasally of 1.5 Lf TT. The composition used for the prime administration is tetanus toxoid in phosphate buffer solution (PBS) for both groups, but the composition used for the boost administration for one group (Group 14) includes both the F127 polymer and chitosan and for the other group (Group 13) includes chitosan but not the F127 polymer. Data for IgG anti-tetanus toxoid antibody titers for blood serum samples taken at weeks 6, 8 and 10 following the prime administration (2, 4 and 6 weeks following the boost) are summarized graphically in Figure 5. As clearly shown in Figure 5, the IgG antibody titers for Group 14 mice are significantly higher at two weeks and four weeks following the boost, even though at 6 weeks following the boost the IgG antibody titers are somewhat higher for Group 13 mice. The enhanced performance at 2 and 4 weeks following the boost is significant, especially when considering that the vertical axis of Figure 5 has a logarithmic scale.

In Example 7, two different groups of outbred, CD-1, female mice are immunized once by subcutaneous administration with 1.5 Lf TT. The test composition that is administered to one group of mice (Group 17) includes the F127 polymer and chitosan, while the test composition that is administered to a second group of mice (Group 18) includes chitosan but not the F127

polymer. A third group of mice (Group 19) receives a subcutaneous administration of 1.5 Lf TT adsorbed to alum each month for three months (for a total of 4.5 Lf TT per mouse). Data for IgG anti-tetanus toxoid antibody titers for blood serum samples taken periodicaly over 20 weeks following adminstration are plotted versus time in Figure 7. As clearly shown in Figure 7, all reported antibody titers for Group 17 mice are significantly higher than for Group 19 mice during the entire 20-week period. Also, except for data taken at one week following administration, the IgG antibody titers for Group 18 are also higher than for Group 19 mice. The reported IgG antibody titers for Group 17 mice are higher than for the Group 18 mice during the 20-week period, although the difference appears to be narrowing in the vicinity of 20 weeks. Importantly, at one week and two weeks following administration the plot indicates that the IgG antibody titers for Group 17 are over twice as large as for the Group 18 mice. Again, it is noted that the IgG antibody titers are plotted on a logarithmic vertical scale.

Also enclosed is a Rule 132 Declaration of Claire M. Coeshott concerning the significant and unexpected nature of results demonstrated during testing of compositions of the invention. The Examiner's attention is particularly directed to the data and discussion in Dr. Coeshott's Declaration concerning Examples 12 and 14 of the Declaration, which examples compare performance of compositions of the invention including an antigen (tetanus toxoid), F127 polymer and an adjuvant (chitosan or CpG dinucleotide motifs) with comparison compositions including the antigen and either the F127 polymer or the adjuvant. In those examples, test compositions of the invention including both the F127 polymer and the adjuvant elicits enhanced immune responses relative to each of the comparison compositions that include only the F127 polymer or only the adjuvant.

The rejections under 35 U.S.C. §103(a) should be withdrawn.

It is believed that all of the issues raised in the Office Action have been addressed herein. Should the Examiner maintain any of the rejections of any of the pending claims, it is respectfully requested that it be pointed out with particularity how the cited reference(s) meet each and every term of each claim with respect to which rejection is maintained. In the absence of a persuasive showing to that effect, all pending claims should be allowed.

A three month extension of time to respond is requested, and enclosed herewith is a petition for such a three month extension of time under 37 C.F.R. §1.136(a) and a check in the

amount of $465 for the fee provided in 37 C.F.R. §1.17(a)(3). No additional fees are believed to be due with this communication. If, however, any additional fees are due, please debit such fees to Deposit Account No. 50-1419. Credit any over payments to Deposit Account No. 50-1419.

The application is believed to be in condition for allowance and allowance of all pending claims is earnestly requested. If the Examiner believes that it would be helpful to discus any of the amendments or remarks presented herein, the Examiner is respectfully invited to contact the undersigned at the telephone number provided below.

Respectfully submitted,

MARSH FISCHMANN & BREYFOGLE LLP

By: _____

Ross E. Breyfogle, Esq.
Registration No. 36,759
3151 South Vaughn Way, Suite 411
Aurora, Colorado 80014
(303) 338-0997

Date: April 22, 2003

VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Amended) ~~An immunogen~~ A composition for delivery of an antigen for stimulation of an immune response when administered to a host, the ~~immunogen~~ composition comprising:

an antigen, ~~a biocompatible~~ polyoxyalkylene block copolymer and ~~a~~ an aqueous liquid ~~vehicle~~;

the polyoxyalkylene block copolymer being biocompatible, not having toxic or injurious effects on biological function in the host when the composition is administered;

wherein, the copolymer interacts with the liquid ~~vehicle~~ to impart reverse thermal viscosity behavior to the composition, so that the viscosity of the composition increases when the temperature of the composition increases over ~~at least~~ some temperature range within a range of from 1 °C to 37 °C; and

wherein, the composition further comprises an additive enhancing the immune response when the composition is administered to the host, the additive being ~~selected from the group consisting of a penetration enhancer,~~ an adjuvant other than alum ~~and combinations thereof~~.

4. (AMENDED) The ~~immunogen~~ composition of Claim 1~~2~~, wherein the composition is in the form of a flowable medium ~~at least~~ when the composition is at a first temperature in the temperature range and the composition is in a gel form ~~at least~~ when the composition is at a second temperature in the temperature range, the second temperature being higher than the first temperature.

5. (AMENDED) The ~~immunogen~~ composition of Claim 4, wherein the first temperature is in a range of from 1 °C to 20 °C.

6. (AMENDED) The ~~immunogen~~ composition of Claim ~~43~~, wherein the first temperature is in a range of from 1 °C to 20 °C and the second temperature is in a range of from 25° C to 37 °C.

7. (AMENDED) The ~~immunogen~~ composition of Claim 4, wherein the copolymer is substantially all dissolved in the liquid ~~vehicle~~ when the ~~immunogen~~ composition is at the first temperature, and at least a portion of the copolymer comes out of solution in the liquid ~~vehicle~~ when the temperature of the composition is raised from the first temperature to the second temperature.

9. (AMENDED) The ~~immunogen~~ composition of Claim 1~~8~~, wherein the polyoxyalkylene block copolymer comprises at least one block of a first polyoxyalkylene and at least one of second polyoxyalkylene.

10. (AMENDED) The ~~immunogen~~ composition of Claim 9 wherein the first polyoxyalkylene is polyoxyethylene and the second polyoxyalkylene is polyoxypropylene.

11. (AMENDED) The ~~immunogen~~ composition of Claim 10, wherein the polyoxyalkylene block copolymer has the formula:

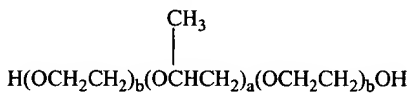
$HO(C_2H_4O)_b(C_3H_6O)_a(C_2H_4O)_bH$

wherein a and each b are independently selected integers.

12. (AMENDED) The ~~immunogen~~ composition of Claim 11, wherein the $(C_2H_4O)_b$ blocks together comprise at least 70 weight percent of the polyoxyalkylene block copolymer.

13. (AMENDED) The ~~immunogen~~ composition of Claim 11 wherein a is between 15 and 80 and each b is independently between 50 and 150.

14. (AMENDED) The ~~immunogen~~ composition of claim 10, wherein the polyoxyalkylene block copolymer has the formula:



wherein a is 20 to 80 and each b is independently 15 to 60.

15. (AMENDED) The ~~immunogen~~ composition of Claim 1, wherein the antigen is ~~derived from at least one~~ selected from the group consisting of bacteria, protozoa, fungus, hookworm, virus and combinations thereof.

16. (AMENDED) The ~~immunogen~~ composition of Claim 1, wherein the antigen is selected from the group consisting ~~comprises at least one~~ of tetanus toxoid, diphtheria toxoid, a non-pathogenic mutant of tetanus toxoid, a non-pathogenic mutant of diphtheria toxoid and combinations thereof.

17. (AMENDED) The ~~immunogen~~ composition of Claim 1, wherein the antigen ~~comprises at least one antigen~~ is from Bordatella pertussis.

18. (AMENDED) The ~~immunogen~~ composition of Claim 1, wherein the antigen ~~comprises at least one antigen~~ is from influenza virus.

19. (AMENDED) The ~~immunogen~~ composition of Claim 1, wherein the antigen ~~comprises~~

~~at least one antigen~~ is from M. tuberculosis.

20. (AMENDED) The ~~immunogen~~ composition of Claim 1, wherein the antigen immunizes against a ~~is derived from at least one causative agent of~~ childhood illness.

21. (AMENDED) The ~~immunogen~~ composition of Claim 1, wherein the antigen ~~comprises at least one of~~ is from rotavirus ~~and at least one antigen derived from rotavirus~~.

22. (AMENDED) The ~~immunogen~~ composition of Claim 1, wherein the antigen is selected from the group consisting of ~~comprises at least one of~~ a polysaccharide, a peptide mimetic of a polysaccharide, an ~~or~~ antigen from Neisseria meningitiditis, ~~and~~ an antigen from Streptococcus pneumoniae and combinations thereof.

23. (AMENDED) The ~~immunogen~~ composition of Claim 1, wherein the antigen is from ~~comprises~~ Epstein-Barr virus ~~or at least one antigen derived from Epstein-Barr virus~~.

24. (AMENDED) The ~~immunogen~~ composition of Claim 1, wherein the antigen is from ~~comprises~~ Hepatitis C virus ~~or at least one antigen derived from Hepatitis C virus~~.

25. (AMENDED) The ~~immunogen~~ composition of Claim 1, wherein the antigen ~~comprises~~ is from HIV ~~or at least one antigen derived from HIV~~.

26. (AMENDED) The ~~immunogen~~ composition of Claim 1, wherein the antigen comprises a ~~at least one~~ molecule involved in a mammalian reproductive cycle.

27. (AMENDED) The ~~immunogen~~ composition of Claim 1, wherein the antigen is ~~comprises~~ HCG.

28. (AMENDED) The ~~immunogen~~ composition of Claim 1, wherein the antigen is a ~~comprises at least one~~ tumor-specific antigen.

29. (AMENDED) The ~~immunogen~~ composition of Claim 1, wherein the antigen ~~comprises at least one antigen~~ is from a blood-borne pathogen.

30. (AMENDED) The ~~immunogen~~ composition of Claim 1, wherein the antigen is a first antigen and the composition comprises a second ~~contains at least two~~ antigens.

31. (AMENDED) The ~~immunogen~~ composition of Claim 30~~1~~, wherein the ~~antigen~~ ~~comprises a~~ first antigen is ~~component~~ selected from the group consisting of tetanus toxoid, a nonpathogenic mutant of tetanus toxoid and combinations thereof; and

the second antigen ~~comprises a second component~~ is selected from the group consisting of diphtheria toxoid, a nonpathogenic mutant of diptheria toxoid and combinations thereof.

33. (AMENDED) The ~~immunogen~~ composition of claim 1, wherein the adjuvant comprises dimethyl dioctadecyl ammonium bromide (DDA).

34. (AMENDED) The ~~immunogen~~ composition of Claim 1, wherein the adjuvant comprises a ~~C$_p$G~~ CpG motif.

35. (AMENDED) The ~~immunogen~~ composition of Claim 1, wherein the adjuvant comprises a cytokine.

36. (AMENDED) The ~~immunogen~~ composition of claim 1, wherein the adjuvant comprises chitosan material.

37. (AMENDED) The ~~immunogen~~ composition of claim 36, wherein the adjuvant comprises N,O-carboxymethyl chitosan.

38. (AMENDED) The ~~immunogen~~ composition of claim 1, wherein the liquid ~~vehicle~~ comprises from 60 weight percent to 85 weight percent of the composition, the antigen comprises from 0.0001 weight percent to 5 weight percent of the composition, the copolymer comprises from 5 weight percent to 33 weight percent of the composition and the additive comprises from 0.01 weight percent to 10.0 weight percent of the composition.

39. (AMENDED) The ~~immunogen~~ composition of Claim 1, wherein the composition is in the form of disperse droplets in a mist.

40. (AMENDED) The ~~immunogen~~ composition of Claim 39, wherein ~~a~~ the mist is produced by a nebulizer.

41. (AMENDED) The ~~immunogen~~ composition of Claim 1, wherein the composition is contained within a nebulizer actuatable to produce a mist comprising dispersed droplets of the composition.

42. (AMENDED) The ~~immunogen~~ composition of Claim 40, wherein the nebulizer is a nasal nebulizer.

43. (AMENDED) The ~~immunogen~~ composition of claim 1, wherein the composition is contained within an injection device that is actuatable to administer the composition to the host by injection.

44. (AMENDED) A method of packaging and storing the ~~immunogen~~ composition of claim 5, comprising placing the composition in a container when the composition is in the form

of a flowable medium and, after the placing, raising the temperature of the composition in the container to convert the composition to the gel form for storage, wherein the gel form in the container can be converted back to the form of a flowable medium for administration to the host by lowering the temperature of the composition in the container.

LANTECH, INC., Plaintiff-Appellee, v. KEIP MACHINE COMPANY, Defendant-Appellant.

93-1457

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

32 F.3d 542; 1994 U.S. App. LEXIS 20586; 31 U.S.P.Q.2D (BNA) 1666

August 5, 1994, Decided

PRIOR HISTORY:
[**1] Appealed from: United States District Court Western District of Michigan. Judge Enslen.

COUNSEL:
Kenneth E. Payne, Attorney, Finnegan, Henderson, Farabow, Garrett & Dunner, of Washington, D.C., argued for plaintiff-appellee. With him on the brief was Dennis P. O'Reilley. Of counsel was Martin I. Fuchs, Finnegan, Henderson, Farabow, Garrett & Dunner. Also on the were James R. Peterson and James S. Brady, of Miller, Johnson, Snell & Cummiskey, of Grand Rapids, Michigan.

Douglas A. Dozeman, Attorney, Warner, Norcross & Judd, of Grand Rapids, Michigan, argued for defendant-appellant. With him on the brief were Charles E. Burpee and James Moskal.

JUDGES:
Before RICH, Circuit Judge, BENNETT, Senior Circuit Judge, and CLEVENGER, Circuit Judge.

OPINIONBY:
RICH

OPINION:

[*543] RICH, Circuit Judge.

Keip Machine Company (Keip) appeals the June 11, 1993, judgment of the United States District Court, Western District of Michigan, Civil Action No. 1:91-CV-721, granting Lantech, Inc.'s (Lantech) motion for summary judgment of infringement, and denying Keip's cross-motion for summary judgment of non-infringement. For the reasons discussed below, we reverse the judgment granting summary judgment of infringement, [**2] reverse-in-part the judgment denying Keip's cross-motion for summary judgment of non-infringement to the extent we find no literal infringement, and remand for further proceedings regarding infringement by application of the doctrine of equivalents which Lantech asserted but the district court did not reach.

Lantech sued Keip for infringement of U.S. Patent No. *4,317,322* (the *'322* patent). Lantech and Keip filed cross-motions for summary judgment. The district court found that Keip's device literally infringed claims 1, 15, and 16 of the *'322* patent. Only the issue of literal infringement is before us on appeal. n1

n1 Because the district court did not decide the issue of infringement by application of the doctrine of equivalents, that issue is not before us on appeal. *Pfaff v. Wells Elecs., Inc., 5 F.3d 514, 519, 28 USPQ2d 1119, 1124 (Fed. Cir. 1993);* See *Cicena, Ltd. v. Columbia Telecommunications Group, 900 F.2d 1546, 1552, 14 USPQ2d 1401, 1407 (Fed. Cir. 1990).*

[**3]

I. Background

A. Technology

The *'322* patent and Keip's allegedly infringing device relate to stretch wrapping machines that spirally wrap packaged products with a pre-stretched film which contracts around the products to protect and hold them together during shipment. The following schematic

diagrams are offered as an aid to understanding their structure.

SEE *'322* IN ORIGINAL

SEE Keip's device IN ORIGINAL

B. Claimed Invention

An embodiment of the *'322* patent, entitled "Rotatable Film Wrapping Apparatus with Wrap Carrying Mechanism," as shown in Fig. 2 below, includes an infeed conveyor 12 on the left and a take-off conveyor 20 on the right. The load 24 to be wrapped passes from left to right through the wrapping station 41 which includes the film dispensing apparatus 16 and the conveyor assembly 14. The rotation of the film dispensing mechanism 16 with the film roll 56 wraps the load **[*544]** 24 as it advances. The conveyor assembly 14, at issue here, has two stacked endless belt conveyors 92 and 94, one above the other. The upper run 98 of conveyor 92 and the lower run 96 of conveyor 94 travel in the same direction at the same speed, carrying the wrapped load 22 to **[**4]** the take-off conveyor 20.

The reason for using two superposed conveyors is that the film gets wrapped around the conveyor as well as the load and has to be carried along with it, contracting against the bottom of the load as it leaves the conveyors due to its residual elasticity.

SEE FIGURE 2 IN ORIGINAL

B. Claims

The dispute has been narrowed to the elements recited in claims 1, 15, and 16 that are directed to the conveying assembly, set forth below. (emphasis added). The numerals in brackets refer to elements circled in Fig. 2.

Claim 1 (in part)

... said conveyor assembly [14] comprising at least two conveyor means [92, 94] ... one of said conveyor means [92] being adapted to receive a load [24] from said infeed means [12] and transport said load [24] ... to contact and wrap the other conveyor means [94] with film [56] dispensed from said film dispensing means [16] enabling the wrapped load [22] on the one conveyor means [92] and the film web wrapped around the other conveyor means [94] to be carried linearly by both conveyor means [14] at substantially the same speed ...

Claim 15 (in part)

... said conveyor assembly [14] comprising **[**5]** two vertically positioned conveyors [92, 94] ... drive means to drive said conveyors so that the upper portion [98] of one conveyor [92] travels in the same direction as the lower portion [96] of the other conveyor [94] with said one conveyor [92] supporting and linearly conveying said load [24] ... to rotate said film roll support member so that it continuously dispenses the material around the said conveyor assembly [14] and the load [24] being supported by the one conveyor [92] to contact and wrap the load [24] and said other conveyor [94] forming a spiral wrapped load [22] ....

Claim 16 (in part)

... **[*545]** said conveyor assembly [14] comprising at least two conveyors [92, 94] positioned adjacent to each other in a stacked relationship and driven at substantially the same speed, one of said conveyors [92] of said conveyor assembly [14] being adapted to receive a load [24] from said conveyor means and transport said load [24] in a downstream direction through and away from said wrapping area, another of said conveyors [94] being adapted to receive and carry film web wrapped around it in said downstream direction, said wrapping means **[**6]** dispensing film from said film dispenser around said load [24] and the lowest conveyor [94] with the film web engaging and being carried by said lowest conveyor [94] at substantially the same speed as the load [24] is being carried by the one conveyor [92] of the conveyor assembly [14] ....

C. Accused Device

Keip's allegedly infringing device is an embodiment of the device shown in U.S. Patent No. *4,979,358* (*'358* patent). Fig. 3 thereof, a top view of the discharge end of the conveyor, and Fig. 9, a cross-sectional view taken on the line IX-IX of Fig. 3, are reproduced below. n2

n2 The parties stipulated that the allegedly infringing machines sold by Keip were accurately depicted in Figs. 1-9 of the *'358* patent.

SEE FIGURE 3 IN ORIGINAL

SEE FIGURE 9 IN ORIGINAL

(some numbers redacted)

Keip's device has a single conveyor that includes two loops or conveyor halves 173 placed horizontally side by side. Each loop 173 comprises a single chain with a plurality of identical one-piece, U-shaped **[**7]**

resilient plastic lugs 177. The outer sides of the lugs, referred to as outer arms 179 and 181, Fig. 9, are expanded as they are carried over longitudinal stationary cam plates 208 and 210 for the entire length of the conveyor along the outer or forward path 178, Fig. 3. When expanded, arms 179 and 181 of the loops 173 cooperate to carry the product and the film forward through and out of the wrapping area. As the resilient lugs reach the discharge end of the conveyor, arms 179 and 181 recoil. The lugs are in their recoiled position for the entire length of the conveyor along inner or return path 180 that does not have cam plates 208 and 210. When moving along the return path 180, Fig. 3, recoiled arms 179 and 181 do not interfere with the forward movement of the load and film. The recoil or collapse of the outer arms 179 and 181 occurs as the chains are rounding the ends 176 of the loops.

II. Analysis

On appeal of a grant of summary judgment, we independently determine whether there are any genuine issues of material fact, and if not whether the court erred either in interpreting the governing law or in applying the law to the facts. *C.R. Bard, Inc. v. Advanced Cardiovascular Sys., Inc., 911 F.2d 670, 673, 15 USPQ2d 1540, 1543 (Fed. Cir. 1990).* **[**8]** Reversal is proper if the court "engaged in a faulty legal analysis in applying the law to the facts and the correct application of the law to those facts might **[*546]** bring a different result." *Litton Industrial Prod., Inc. v. Solid State Sys. Corp., 755 F.2d 158, 164, 225 USPQ 34, 38 (Fed. Cir. 1985).* The district court is required to view the evidence in the light most favorable to the party opposing the motion. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 89 L. Ed. 2d 538, 106 S. Ct. 1348 (1986).*

The issue before us is whether the district court properly granted summary judgment in finding that Keip's device literally infringes claims 1, 15, and 16 of the *'322* patent. Determining whether the claims of a patent have been literally infringed is a two step process: first, the claims must be interpreted to determine their proper scope; thereafter, the claims as thus interpreted are applied to the accused device. *Palumbo v. Don-Joy Co., 762 F.2d 969, 974-75, 226 USPQ 5, 7 (Fed. Cir. 1985).*

A. Claim Interpretation

[9]**

Claim interpretation is a question of law amenable to summary judgment. Mere disagreement over the meaning of a term does not necessarily give rise to a genuine issue of material fact. *Intellicall, Inc. v. Phonometrics, Inc., 952 F.2d 1384, 1387, 21 USPQ2d 1383, 1386 (Fed. Cir. 1992).* To determine the intended meaning of a claim, we look to the claim language in context of the specification and the prosecution history. *C.R. Bard, 911 F.2d at 673, 15 USPQ2d at 1543.*

Keip argues that the district court's interpretation of the claim language was erroneous. We agree. The district court erred first by ignoring the "at least two" claim limitation, and second, by embracing an erroneous interpretation of the term "conveyor."

Before the district court, Keip argued that the conveyor assembly, as defined by the claims, is required to have the following elements:

1. At least two conveyors n3 [means]; n4

2. One conveyor [means] that is adapted to receive the load and convey it across the gap; and

3. One conveyor [means] that is adapted to contact the film and convey the film web across **[**10]** the gap.

n3 Claims 15 and 16.

n4 Claim 1 employs means-plus-function language.

The district court disagreed and concluded that Keip could not avoid literal infringement by reading in limitations that were not in the claims. The limitations, however, are in the claims. The district court's error can be traced to its reiteration of the claims just prior to its analysis wherein it omitted the "at least two" language from the claims. Based on the thus redacted claims, the district court stated: "There is no word or phrase which requires the conveyor means or conveyors to be structurally independent of each other." No. 1:91:CV:721, slip op. at 12. That omission effectively read out the "at least two" limitation which is clearly stated in the claims.

All limitations in a claim must be considered meaningful. See *Perkin-Elmer Corp. v. Westinghouse Elec. Corp., 822 F.2d 1528, 1532-33, 3 USPQ2d 1321, 1324-25 (Fed. Cir. 1987).* Indeed, the language of the claims makes unambiguous **[**11]** reference to two distinct elements of the claimed structure: first by the "at least two conveyor [means]" language, and second by the "one of said conveyor [means]," "other conveyor means," "both conveyor means," and "lowest conveyor" language. It is clear that the claims define two separate conveyor structures; otherwise the recitation of the "at least two" limitation would be meaningless.

When claiming a combination where more than one of a certain element, here a conveyor [means], is included in the combination, the term "at least two" sets forth the minimum number of a particular element required. This interpretation gives full effect to the recitation of two distinct elements in the claimed structure. Therefore, properly interpreted, all claims at issue require two or more conveyor structures, not one. Accordingly, we interpret claims 1, 15, and 16 to require two separate conveyors.

Having properly put back into the claims the "at least two" limitation, we next interpret **[*547]** the term "conveyor." "Terms in claims are to be given their ordinary and accustomed meaning, unless it appears that the inventor used them differently." *Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 759, 221 USPQ 473, 477 (Fed. Cir. 1984).* **[**12]** The term conveyor is neither ambiguous nor highly technical. More importantly, there is nothing in the claims, the specification or prosecution history that would suggest a meaning other than its ordinary meaning.

The district court properly concluded that the ordinary meaning of conveyor was applicable and correctly set forth its meaning as "an apparatus that transports articles from one place to another." n5 Nevertheless, as discussed below, the district court subsequently embraced Lantech's erroneous "conveying or moving surface" definition. The term conveyor, as used in the claims and described in the specification always refers to an operative device or structure which would ordinarily be considered a conveyor. A conveyor necessarily includes components such as belts, slider plates, and drives, in addition to a moving surface.

n5 As defined in the American Heritage Dictionary of the English Language (1981).

The claims require two or more conveyors or conveyor means and not two or more moving surfaces. There is **[**13]** nothing in the specification or prosecution history to suggest that a conveyor is defined as merely a moving surface. While a conveyor has a moving surface, a moving surface alone is not a conveyor.

The district court erred as a matter of law by effectively reading out a specific and clearly stated limitation, and embracing an erroneous interpretation of the term conveyor. Properly construed, the claims require at least two conveyors which are separate elements and not merely two moving surfaces.

B. Literal Infringement

Literal infringement is found where the accused device falls within the scope of the asserted claims as properly interpreted. *Palumbo, 762 F.2d at 974, 226 USPQ at 7.* For literal infringement, each limitation of the claim must be met by the accused device exactly, any deviation from the claim precluding a finding of infringement. *Johnston v. IVAC Corp., 885 F.2d 1574, 1577, 12 USPQ2d 1382, 1384 (Fed. Cir. 1989).*

Only one conveyor can be found in the Keip device. The conveyor that is contacted and wrapped by the film is the same conveyor that transports the product. In **[**14]** fact, before the court misinterpreted the claims, it correctly stated that the Keip device "utilizes a single conveyor consisting of two endless loops, or conveyor halves, placed horizontally side-by-side" (emphasis added). slip op. at 8. Neither the right nor the left conveyor loop of the Keip device is by itself a conveyor because neither half is capable of functioning as a conveyor. We therefore find that Keip's device does not literally infringe the asserted claims because it does not have two conveyors as required by each of the claims in suit.

Lantech argues that because the arms 179, 181 on the lugs constitute two discrete moving or conveying surfaces, these surfaces are equal to two conveyors. This argument is not persuasive. While the upper and lower arms of the chain-supported lugs, which make up the loops, contact and move both the product and the film, they are not in and of themselves separate conveyors. The district court failed to distinguish between two separate conveyors and a single conveyor with two moving surfaces going in the same direction. The claims define the former and cannot literally be literally read on the latter. On this basis alone, there **[**15]** can be no literal infringement because Keip's device lacks a second conveyor.

Having fully considered the remaining arguments of both parties we find it unnecessary to address them in light of the above conclusions.

CONCLUSION

Contrary to the district court's opinion, the record does not support its claim interpretation or its finding of literal infringement. Accordingly, as to the judgment granting Lantech's motion for summary judgment of literal infringement, we reverse.

[*548] As to the judgment denying Keip's motion for summary judgment of non-infringement, to the extent we find no literal infringement, we reverse.

We remand for further proceedings regarding infringement by application of the doctrine of

equivalents, asserted by plaintiff but not decided by the district court.

REVERSE; REVERSE-IN-PART, AND REMAND

COSTS

Each party is to bear their own costs.

QUANTUM CORPORATION, Plaintiff-Appellee, v. RODIME, PLC, Defendant-Appellant.

94-1296

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

65 F.3d 1577; 1995 U.S. App. LEXIS 27162; 36 U.S.P.Q.2D (BNA) 1162

September 22, 1995, Decided

SUBSEQUENT HISTORY:
[1]**

Rehearing Denied and In Banc Suggestion Declined November 27, 1995, Reported at: *1995 U.S. App. LEXIS 35098.* Certiorari Denied April 29, 1996, Reported at: *1996 U.S. LEXIS 2830.*

PRIOR HISTORY:
Appealed from: United States District Court for the District of Minnesota. Judge Doty.

DISPOSITION:
AFFIRMED

COUNSEL:
John F. Lynch, Attorney, Arnold, White & Durkee, Houston, Texas, argued for plaintiff-appellee. With him on the brief were Richard L. Stanley, J. Mike Amerson, and Gary J. Fischman. Of counsel David B. Harrison, Quantum Corporation, Milpitas, California, and Terence M. Fruth, Fruth and Anthony, PA., Minneapolis, Minnesota.

Margaret F. Pfeiffer, Attorney, Sullivan and Cromwell, Washington, D.C., argued for defendant-appellant. Of counsel were Robert A. Sacks, Sullivan and Cromwell, Washington, D.C., and John C. Altmiller, Kenyon and Kenyon, Washington, D.C.

JUDGES:
Before PLAGER, LOURIE, and RADER, Circuit Judges.

OPINIONBY:
PLAGER

OPINION:

[*1578] PLAGER, ***Circuit Judge.***

The question in this declaratory judgment action is whether amendments made during a prior reexamination proceeding impermissibly broadened the scope of the patent claims at issue in violation of *35 U.S.C. § 305* (1988), n1 and, if so, the legal effect thereof. Defendant patentee Rodime PLC (Rodime) appeals the decision of the United States District Court for the District of Minnesota, Civil Action No. 4-93-214. In **[**2]** its decision, the district court granted Quantum Corporation's (Quantum) motion for summary judgment that Claims 4, 6, 7, 9, 14 and 19-27 of U.S. Patent No. B1 *4,638,383* (the reexamined *'383* patent) are invalid because they were impermissibly broadened during reexamination. We ***affirm***.

n1 Unless specified otherwise, all cites to the United States Code are for the year 1988.

I. BACKGROUND

A.

Rodime is the owner of the reexamined *'383* patent, which issued on November 29, 1988. The reexamined *'383* patent is directed to a micro hard-disk drive system (3.5 inch drive) suitable for use in portable computers with performance parameters comparable to those available in 5.25 inch disk drive systems. Quantum, the plaintiff in this declaratory judgment action, is the manufacturer of disk drives which, Rodime alleges in its counterclaim, infringe its patent.

The claim limitation at issue in this appeal relates to the storage capability of the hard-disk. The storage capability of a hard-disk is a function **[**3]** of the track density; the greater the track density, the more data that can be stored in a given area of the disk. Track density may be defined in terms of "tracks per inch" (tpi), calculated based on the number of concentric tracks present within an inch along the radius of the hard-disk.

On November 19, 1985, James G. McGinley and Roderick M. Urquhart, two engineers at Rodime, filed a patent application for the invention described above. Claim 1 of this application recited, ***inter alia***, a track density of "approximately 600" tpi. The examiner, in a first office action, rejected all the claims as obvious under *35 U.S.C. § 103*. With respect to the track density limitation in Claim 1, the examiner stated:

The art described in the preceding paragraph [regarding 5.25 inch disks] demonstrates that such a density is within the state of the art. Such a density would seemingly be achievable on a [3.5 inch] disk in the same manner by which it was achieved on a larger disk. Consequently it would seem that the subject matter of claim 1 - which is seemingly quite general - should not be considered patentable.

In a response dated May 23, 1986, applicants cancelled **[**4]** the original claims and inserted new claims some of which recited a track density of "at least 600" tpi. Although applicants had replaced "approximately" with "at least" in the track density limitation of these new claims, they made no reference to this in their response, but instead focused on the difference between the size of their disks (3.5 inch) and those in the prior art (5.25 inch) as a basis for overcoming the examiner's rejection. The examiner subsequently allowed these new claims, and the patent issued on **[*1579]** January 20, 1987, as U.S. Patent No. *4,638,383* (the original *'383* patent). Claims 4, 6, 7, 9, and 14 of the original *'383* patent all recited a track density of "at least 600 concentric tracks per inch."

On September 28, 1987, Rodime, the owner of the original *'383* patent pursuant to an assignment from the inventors, requested reexamination of its patent. Finding a substantial new question of patentability, ***see*** *35 U.S.C. § 303*, the United States Patent and Trademark Office (PTO) granted Rodime's request for reexamination of all 16 claims in the original *'383* patent. In an office action dated April 19, 1988, the examiner rejected all but two of the original claims. **[**5]** Rodime responded by cancelling certain claims, amending others, and adding dependent Claims 17-31. With respect to the claims at issue in this appeal, Rodime made substantial amendments including changing the track density limitation from "at least 600" tpi to "at least approximately 600" tpi. These claims were allowed, as amended, and the *'383* reexamined patent issued on November 29, 1988, as U.S. Patent No. B1 *4,638,383*. As issued, independent Claims 4, 6, 7, 9, and 14 of the reexamined *'383* patent all recite a track density of "at least approximately 600" tpi, and the newly added dependent claims which are at issue in this appeal, i.e. Claims 19-27, either explicitly contain this limitation or incorporate it through their dependency. n2

n2 Illustrative of the amendments made is Claim 4 with the sections within the brackets being the matter that was deleted and the underlined sections indicating the additions made to the claim during reexamination:

4. A computer disk drive system **[for operating a micro hard-disk, said disk drive system]** comprising:

a sealed housing;

at least **[one]** two micro **[hard-disk]** hard-disks each having a diameter of between 92 and 96 millimeters and each having a plurality of concentrically adjacent tracks on both planar sides thereof, said micro hard-disks fixedly mounted in **[a]** the sealed housing;

means for rotatably supporting said **[hard-disk]** micro hard-disks;

means for rotating said **[hard-disk]** micro hard-disks;

first and second transducer means **[having two read/write heads]** for writing digital information on and reading digital information from said **[hard-disk]** micro hard-disks on both planar sides of **[said]** each micro hard-disk in a format so that **[said]** each micro hard-disk has digital information stored on **[concentric]** said concentrically adjacent tracks at a density providing at least 5 Megabytes of storage per **[disk]** micro hard-disk with the digital information being stored at a density of at least **[6000]** approximately 600 concentric tracks per inch, said first and second transducer means each comprising two read/write heads; **[and,]**

positioning means for moving said first and second transducer means between the concentrically adjacent tracks on said **[hard-**

disk] micro hard-disks, said positioning means including:

a positioning arm disposed within the sealed housing and mounted for movement relative to said micro hard-disks;

a pivot shaft coupled to one end of said positioning arm and supporting said positioning arm for rotational movement relative to said micro hard-disks, four support arms, each supporting one of said heads at one end and each connected to said positioning arm at its other end; and

means for moving said positioning arm including a stepper motor having a shaft extending into said sealed housing and means for operating said stepper motor in step increments, each increment causing **[said transducer means]** said read/write heads to move from one track to the next adjacent track on said **[hard-disk]** micro hard-disks.

[6]**

B.

Quantum filed the present action in the United States District Court for the District of Minnesota on February 26, 1993, seeking a declaration that the reexamined *'383* patent is invalid, unenforceable and not infringed. Rodime subsequently filed an answer and a counterclaim for infringement. On February 22, 1994, Quantum filed a motion for summary judgment that Claims 4, 6, 7, 9, 14, and 19-27 of the reexamined *'383* patent are invalid under *35 U.S.C. § 305* for being impermissibly broadened by Rodime during reexamination. According to Quantum, Rodime's amendment during reexamination of the track density limitation from "at least 600" tpi to "at least approximately 600" tpi broadened the scope of the claims to cover certain disk drives with approximately but less than 600 tpi that were not covered by the original *'383* patent claims, and therefore these claims are invalid under *35 U.S.C. § 305*.

[*1580] The district court, in an order dated April 11, 1994, granted Quantum's motion for summary judgment. The court, after examining the claims, specification, and prosecution history, concluded that the addition of the word "approximately" to the track density limitation during reexamination **[**7]** was not a mere clarification, as Rodime argued, but was instead a substantive change that expanded the scope of the claims at issue in violation of *35 U.S.C. § 305*, and that no reasonable juror could have found otherwise. In support, the court relied on the difference in the ordinary meaning of the disputed claim limitations: a track density of "at least 600 tpi" indicates densities starting at, but greater than 600 tpi, whereas the addition of "approximately" in the track density limitation of the reexamined *'383* patent modifies the 600 tpi value, thereby eroding the "not less than" meaning of "at least." Based on these definitions, it followed, according to the court, that the claims had been broadened during reexamination since the reexamined *'383* patent covered devices with track densities less than 600 tpi that were not covered by the original *'383* patent. The court then concluded, without analysis, that the improperly broadened claims were invalid.

Since the district court's ruling disposed of all the claims which Rodime in its counterclaim had alleged Quantum to infringe, the district court, on April 26, 1994, ordered that final judgment be entered under Fed. R. Civ. P. 58 **[**8]** in favor of Quantum for a declaratory judgment of nonliability and against Rodime for its counterclaim of infringement of the reexamined *'383* patent. This appeal followed.

II. DISCUSSION

There are two issues in this case: first, whether Rodime broadened the scope of the claims at issue during reexamination in violation of *35 U.S.C. § 305* by changing the track density limitation from "at least 600 tpi" to "at least approximately 600 tpi," and, second, assuming the claims were impermissibly broadened, the legal effect of violating section 305. We review the district court's grant of summary judgment in favor of Quantum on these issues -- that the claims were broadened and are therefore invalid -- to determine whether any genuine issues of material fact are in dispute, and whether any errors of law were made. ***London v. Carson Pirie Scott & Co.**, 946 F.2d 1534, 1537, 20 U.S.P.Q.2D (BNA) 1456, 1458 (Fed. Cir. 1991).*

A.

35 U.S.C. § 305 states, in relevant part, that "no proposed amended or new claim enlarging the scope of a claim of the patent will be permitted in a reexamination proceeding." An amended or new claim has been enlarged if it includes within its scope any subject matter **[**9]** that would not have infringed the original patent. ***In re Freeman**, 30 F.3d 1459, 1464, 31 U.S.P.Q.2D (BNA) 1444, 1447 (Fed. Cir. 1994).* "A claim that is broader in any respect is considered to be broader than the original claims even though it may be narrower in other respects." ***Id.*** (quoting ***Tillotson, Ltd. v. Walbro Corp.**, 831 F.2d 1033, 1037 n.2, 4 U.S.P.Q.2D (BNA) 1450, 1453 n.2 (Fed. Cir. 1987)).* Accordingly, the claims at issue have been improperly broadened in violation of *35 U.S.C. § 305* if the track density limitation in the claims of the reexamined *'383* patent -- "at least approximately 600 tpi" -- is broader than the

track density limitation in the claims of the original *'383* patent -- "at least 600 tpi."

Whether claims have been enlarged is a matter of claim construction, a question of law subject to complete and independent review on appeal. ***Id.*** at 1464, 31 U.S.P.Q.2D (BNA) at 1447. When construing the meaning of disputed terms in a claim, we look to the claims, specification and prosecution history. ***Carroll Touch, Inc. v. Electro Mechanical Sys., Inc.,*** *15 F.3d 1573, 1577, 27 U.S.P.Q.2D (BNA) 1836, 1839-40 (Fed. Cir. 1993).* Although a patentee can be his own **[**10]** lexicographer, the words of a claim will be given their ordinary meaning to one of skill in the art unless the inventor appeared to use them differently. ***Hoganas AB v. Dresser Indus., Inc.,*** *9 F.3d 948, 951, 28 U.S.P.Q.2D (BNA) 1936, 1938 (Fed. Cir. 1993).*

Rodime's principle argument on appeal is that the addition of the word "approximately" to the track density limitation only made explicit what was already implicitly included **[*1581]** in the claim, and therefore did not expand the scope of the claims at issue. In support of this proposition, Rodime cites ***Laitram Corp. v. NEC Corp.,*** *952 F.2d 1357, 21 U.S.P.Q.2D (BNA) 1276 (Fed. Cir. 1992),* ***Tennant Co. v. Hako Minuteman, Inc.,*** *878 F.2d 1413, 11 U.S.P.Q.2D (BNA) 1303 (Fed. Cir. 1989),* and ***Kaufman Co. v. Lantech, Inc.,*** *807 F.2d 970, 1 U.S.P.Q.2D (BNA) 1202 (Fed. Cir. 1986).* Specifically, Rodime asserts that to one of skill in the art the term "600 tpi" means "approximately 600 tpi." In support, Rodime proffers the testimony of various technical experts who maintain that, because of manufacturing tolerances and variations inherent in rotary actuator drives, industry literature referring to a specific track density value is understood by those **[**11]** skilled in the art to represent a range. This interpretation, according to Rodime, is consistent with the specification which uses the terms "600 tpi" and "approximately 600 tpi" interchangeably. Since "600 tpi" means "approximately 600 tpi" to one of skill in the art, it necessarily follows, Rodime argues, that one of skill in the art would interpret "at least 600 tpi" to mean "at least approximately 600 tpi." Accordingly, Rodime concludes that the district court erred in not granting summary judgment in their favor, or, at a minimum, concluding that this evidence created a genuine issue of material fact to be resolved at trial.

We disagree. The major flaw in Rodime's argument is that it focuses solely on the term "600 tpi" instead of the claim limitation as a whole, in context. ***See United States v. Telectronics, Inc.,*** *857 F.2d 778, 781, 8 U.S.P.Q.2D (BNA) 1217, 1219-20 (Fed. Cir. 1988),* ***cert. denied,*** *490 U.S. 1046, 104 L. Ed. 2d 423, 109 S. Ct. 1954 (1989).* Even if "600 tpi" means "approximately 600 tpi," as Rodime argues, it is unnecessary to read in an implicit range when interpreting "at least 600 tpi" because this limitation as a whole already expressly represents an open-ended range, i.e. 600 tpi and **[**12]** up. Therefore, that one skilled in the art understands "600 tpi" to connote a range is irrelevant because the limitation in dispute is "at least 600 tpi," and Rodime offered no evidence to show that one skilled in the art understood "at least 600 tpi" to be the same as "at least approximately 600 tpi" or that the patentee defined it as such in the patent or during prosecution.

Absent such a definition or evidence that the claim limitation as a whole has a special meaning to one of skill in the art, we see no error in the district court's use of dictionary definitions to ascertain the ordinary meaning of the relevant claim limitation. ***See, e.g., Hoganas,*** *9 F.3d at 951 n.8, 28 U.S.P.Q.2D (BNA) at 1938 n.8* (using Webster's New World Dictionary, Third Edition, to define the word "straw"). Regarding the limitation "at least 600 tpi," the term "at least" means "as the minimum," **Webster's Third New International Dictionary** 1287 (1986), and therefore when coupled with a specific number sets forth an absolute lower limit of a range, i.e., 600 on up. ***See Lantech, Inc. v. Keip Mach. Co.,*** *32 F.3d 542, 546, 31 U.S.P.Q.2D (BNA) 1666, 1670 (Fed. Cir. 1994)* ("The term 'at least two' **[**13]** sets forth the minimum number of a particular element required."). The addition of "approximately" which means "reasonably close to," n3 eliminates the precise lower limit of that range, and, in so doing extends the scope of the range. The term "at least approximately 600 tpi" therefore defines an open-ended range starting slightly below 600. ***See, e.g., Hybritech, Inc. v. Abbott Labs.,*** *849 F.2d 1446, 1455, 7 U.S.P.Q.2D (BNA) 1191, 1199 (Fed. Cir. 1988)* (reasonable likelihood of success of proving that accused products with affinities of 4.8 x 107 and 7.1 to 7.5 x 107 liters/mole literally infringe patent with a recited claim limitation for affinity of "at least about 108 liters/mole"); ***Ex parte Neuwirth,*** *229 U.S.P.Q. (BNA) 71, 73* (Bd. Pat. App. & Int. 1985) (addition of the word "substantially" during reexamination as a modifier for "rounded bottom wall" broadened the scope of the claim in violation of *35 U.S.C. § 305).*

n3 **Webster's Third New International Dictionary** 107 (1986).

Since the amended limitation **[**14]** includes subject matter not covered by the original claims, i.e. track densities below 600 tpi, we conclude that Rodime expanded the scope of their claims during reexamination in violation of *35 U.S.C. § 305.* To conclude otherwise would force us to alter what Rodime chose to claim as its

invention in the original *'383* patent, i.e., a track density range starting at **[*1582]** 600 tpi. We cannot do that. ***E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.***, *849 F.2d 1430, 1433, 7 U.S.P.Q.2D (BNA) 1129, 1131* (Fed. Cir.), ***cert. denied***, *488 U.S. 986, 102 L. Ed. 2d 572, 109 S. Ct. 542 (1988).*

Seattle Box Co. v. Industrial Crating & Packing, Inc., *731 F.2d 818, 221 U.S.P.Q. (BNA) 568 (Fed. Cir. 1984)* raised similar issues, with similar results. In that case the court evaluated whether a reissued patent claim was "identical" to the original claim. The applicant originally filed a patent application for a device for packaging and safely transporting oil pipes with Claim 1 reciting, ***inter alia***, a spacer block having a height "substantially equal to" the pipe diameter. ***Id.*** *at 821, 221 U.S.P.Q. (BNA) at 571.* Applicants amended this limitation during prosecution, and Claim 1 subsequently issued with a recited **[**15]** spacer block height "greater than" the pipe diameter. ***Id.*** The patentee subsequently amended this claim during reissue to cover a block height "substantially equal to or greater than" the pipe diameter. ***Id.*** *at 822, 221 U.S.P.Q. (BNA) at 571.*

The court, in determining whether the patentee was prohibited under *35 U.S.C. § 252,* para. 1 from collecting damages for activities occurring prior to the issuance of the reissue patent, had to decide whether the patentee had made a substantive change to the claims during reissue. In this regard, the district court stated, and we affirmed, that:

Seattle Box, in broadening its claims' scope to cover not only spacer blocks "greater than" but also "substantially equal to" the diameter of the pipes in a bundle, has, in our view, made substantive change to its claims. The original claims cannot reasonably be read as intending, but for some inaccuracy in their expression, the same coverage as the reissue claims. Here, the addition is not a matter of mere clarification of language to make specific what was always implicit or inherent.

Id. at 828, 221 U.S.P.Q. (BNA) at 575.

The relevant claim language and prosecution history **[**16]** in our case is remarkably similar to that in ***Seattle Box***, and therefore this decision lends further support to the district court's conclusion that the amended claims in our case were also broadened. n4 First, the original claim limitations in both cases used precise language to define the scope of the coverage. In ***Seattle Box***, the original claims recited a spacer block height "greater than" the pipe diameter, whereas in our case the original *'383* patent recited a track density of "at least 600 tpi." Although both claims recite open-ended ranges, the lower limit is clearly defined in each claim. Second, in both cases, the claims at issue were amended to include words effecting a broadening of the claim. In ***Seattle Box***, applicants added the term "substantially equal to" during reissue, whereas in our case the term "approximately" was added during reexamination.

> n4 The test for determining whether a reexamined claim is broader than an original claim under *35 U.S.C. § 305* is the same as that in *35 U.S.C. § 251,* last paragraph, for determining whether reissue claims filed more than two years after issuance of the original patent are broader than the original claims. ***In re Freeman***, *30 F.3d 1459, 1464, 31 U.S.P.Q.2D (BNA) 1444, 1447 (Fed. Cir. 1994).*

[17]**

Finally, in both cases the amended language was initially recited in the claims at issue, but was deleted in response to the examiner's first office action. As mentioned previously, Rodime's initial claims recited a track density of "approximately 600 tpi," but, along with other amendments, were changed to "at least 600 tpi." This not only parallels what occurred in ***Seattle Box***, but it also contradicts Rodime's assertion that "approximately" was added during reexamination to clarify the language in the original *'383* patent. If "approximately" merely clarifies the phrase "at least 600 tpi," it seems unlikely that this supposedly clarifying language would have been deleted, as it was, during the initial prosecution.

In view of all the foregoing, we conclude, as a matter of law, that Rodime broadened the scope of the claims at issue during reexamination in violation of *35 U.S.C. § 305.* Accordingly, we affirm the district court's grant of summary judgment on this issue.

B.

But what are the consequences of such a broadening? Are the claims entirely invalid, or is invalidity limited only to the **[*1583]** broadened aspects of the claims, so that the original scope of the claims remains **[**18]** available to the patentee? The district court's analysis concluded when it determined that the reexamined claims were broader than the original claims in the *'383* patent, apparently believing that it necessarily followed that the claims at issue are therefore invalid. However, the Patent Act is silent regarding the proper remedy to be employed by a district court in a patent infringement suit when it determines that claims were improperly broadened during reexamination in violation of *35 U.S.C. § 305.* Neither the express words in section 305 nor its legislative history provide any guidance in

this situation; they merely recite the prohibition against broadening during reexamination.

35 U.S.C. § 282, which lists various affirmative defenses in a patent infringement suit, allows a defendant in a patent infringement action to assert an invalidity defense based on a failure to comply with any of the statutory requirements in *35 U.S.C. § 251* for ***reissue*** applications. n5 Therefore, a district court could declare that reissued claims are invalid as a matter of law if they were impermissibly broadened in violation of *35 U.S.C. § 251,* para. 4. n6 ***See Tillotson Ltd. v. Walbro*** **[**19]** ***Corp.,*** *831 F.2d 1033, 4 U.S.P.Q.2D (BNA) 1450 (Fed. Cir. 1987)* (reversing a district court's grant of summary judgment of invalidity since genuine issues of material fact existed whether reissued claims filed more than two years after the original patent were broader than the original claims). However, despite the fact that the prohibition in section 251 against enlarging the scope of claims in reissue applications is analogous to the prohibition in section 305 regarding broadening during reexamination, n7 section 282 does not specifically mention section 305 as an invalidity defense in a patent infringement suit.

n5 *35 U.S.C. § 282* reads in relevant part:

> The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:
>
> (1) Noninfringement, absence of liability for infringement or unenforceability,
>
> (2) Invalidity of the patent or any claim in suit on any ground specified in part II of this title as a condition for patentability,
>
> (3) Invalidity of the patent or any claim in suit for failure to comply with any requirement of sections 112 or 251 of this title,
>
> (4) Any other fact or act made a defense by this title.

[20]**

n6 Paragraph 4 of *35 U.S.C. § 251* reads:

> No reissued patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent.

n7 The only difference between the prohibitions against broadening in section 251 and section 305 is that ***reissued*** patent claims can not be broadened more than two years after issuance of the original patent, whereas claims in a ***reexamined*** patent can never be broadened.

Our precedent does not address this issue either. ***In re Freeman,*** *30 F.3d 1459, 31 U.S.P.Q.2D (BNA) 1444 (Fed. Cir. 1994),* was an appeal from a decision of the PTO sustaining an examiner's rejection of claims as impermissibly broadened in violation of section 305. It does not speak to the issue of whether a district court can declare previously issued claims invalid for failure to comply with section 305. ***Fortel Corp. v. Phone-Mate, Inc.,*** *825 F.2d 1577, 3 U.S.P.Q.2D (BNA) 1771 (Fed. Cir. 1987)* was an appeal from a district court decision in which reexamined claims were found to have been **[**21]** broadened during reexamination in violation of section 305, but the issue in that case was whether the patentee could enforce these broader claims against an accused infringer who had ceased his allegedly infringing activity prior to issuance of the reexamined patent. Our court held that since the reexamined claims were broadened they were not substantively identical to the originally issued claims within the meaning of *35 U.S.C. § 252,* para. 1, and therefore the district court properly granted summary judgment that the claims could not be enforced against the defendant. n8 Validity was not at issue in ***Fortel*** because the defendant in ***Fortel,*** unlike the defendant in our case, did not raise it as a defense.

n8 *35 U.S.C. § 307*(b) states that amended or new claims found to be patentable during reexamination will have the same effect as that specified in *35 U.S.C. § 252* for reissued patents.

Despite the absence of specific statutory language or precedent of this court in support of **[**22]** the district court's judgment that the claims at issue are invalid, we conclude that, **[*1584]** as a matter of law, the district court arrived at the correct result. The purpose of the reexamination process is to provide a mechanism for reaffirming or correcting the PTO's action in issuing a patent by reexamining patents thought to be of doubtful validity. ***In re Etter,*** *756 F.2d 852, 857, 225 U.S.P.Q. (BNA) 1, 4* (Fed. Cir.), ***cert. denied,*** *474 U.S. 828, 88 L. Ed. 2d 72, 106 S. Ct. 88 (1985).* Consistent with this overall purpose, Congress enacted section 305 which, while allowing an applicant to amend his claims or add new claims to distinguish his invention over cited prior art, explicitly prohibits any broadening of claims during reexamination. If an applicant fails to claim as broadly as

he or she could have, the proper recourse, if within two years of issuance of the patent, is to file a reissue application, *see 35 U.S.C. § 251,* not to remedy this problem in a reexamination proceeding.

As with violations of other statutes in the Patent Act, claims that do not comply with section 305 cannot stand. Rodime agrees, but maintains that the proper recourse is for this court to exercise its inherent equitable **[**23]** powers by restricting the scope of the claims to their original terms, avoiding a holding of infringement against any devices that would not have been covered by any of the original claims as they existed prior to reexamination. ***See Texas Instruments, Inc. v. United States Int'l Trade Comm'n,*** *846 F.2d 1369, 1371-72, 6 U.S.P.Q.2D (BNA) 1886, 1889 (Fed. Cir. 1988).* We disagree. Although we construe claims, if possible, so as to sustain their validity, ***Carman Indus., Inc. v. Wahl,*** *724 F.2d 932, 937 n.5, 220 U.S.P.Q. (BNA) 481, 485 n.5 (Fed. Cir. 1983),* it is well settled that no matter how great the temptations of fairness or policy making, courts do not redraft claims. ***Autogiro Co. of Am. v. United States,*** *181 Ct. Cl. 55, 384 F.2d 391, 395-96, 155 U.S.P.Q. (BNA) 697, 701 (Ct. Cl. 1967).* Moreover, even if we could consider equities, they do not favor Rodime; they broadened their claims during reexamination despite the explicit prohibition against doing so in section 305.

Likewise, the district court cannot remand the case to the PTO to have the broadening language deleted from the claims. ***Cf. Green v. Rich Iron Co.,*** *944 F.2d 852, 20 U.S.P.Q.2D (BNA) 1075 (Fed. Cir. 1991)* (holding that a district court **[**24]** could not compel a patentee to seek reissue of his patent). To conclude otherwise would discourage instead of encourage compliance with section 305. If the only penalty for violating section 305 is a remand to the PTO to have the reexamined claims narrowed to be commensurate in scope with what the applicant was only entitled to in the first place, then applicants will have an incentive to attempt to broaden their claims during reexamination, and, if successful, be able to enforce these broadened claims against their competitors. This result essentially renders the prohibition in section 305 meaningless. ***See In re Bennett,*** *766 F.2d 524, 530, 226 U.S.P.Q. (BNA) 413, 417 (Fed. Cir. 1985)* (Miller, J., dissenting) ("There is no evidence before this court rebutting the basic presumption that Congress shall not be deemed to have done a futile thing."). The likelihood that improperly broadened claims will be held invalid will discourage applicants from attempting to broaden their claims during reexamination.

Our conclusion that the claims at issue are invalid is not inconsistent with *35 U.S.C. § 282.* Section 282 does not state that the list of invalidity defenses contained therein **[**25]** are the only ones available; the statute merely says "the following shall be defenses." The express words of section 282 therefore allow for the existence of other invalidity defenses.

We conclude that a violation of *35 U.S.C. § 305* is an invalidity defense in a patent infringement action, and therefore the district court, upon finding correctly that the claims at issue were improperly broadened during reexamination in violation of section 305, properly granted Quantum's motion for summary judgment of invalidity. n9

n9 We have considered the other objections to the district court's judgment raised by Rodime in their brief, and find none sufficiently meritorious to require overturning of the district court's judgment.

[*1585] III. CONCLUSION

The judgment of the district court granting summary judgment in favor of Quantum that Claims 4, 6, 7, 9, 14, and 27 of the reexamined *'383* patent are invalid as being improperly broadened during reexamination in violation of *35 U.S.C. § 305,* is

AFFIRMED **[**26]**

functional terms are of any patentable significance, beyond the proportions set out in the allowed claims. It is noted that the tables on page 2 of the specification indicates that the rate of growth declines after a maximum rate of growth is attained as the amount of aspirin in the feed is increased. * * *" (Emphasis supplied)

While there is some doubt that the reference would necessarily make it obvious to do what appellant has done, there can be no doubt that the language, "an effective amount of aspirin for growth stimulation" is functional in nature and of no patentable significance inasmuch as it describes the amount of aspirin merely in terms of the desired result, rather than by the means disclosed for producing that result.

Under certain circumstances "functional" language is permissible, but Congress could not have intended such indiscriminate use as here. As we said in In re Lundberg, 244 F.2d 543, 44 CCPA 909:

"* * * The requirement in the second paragraph of section 112 that 'the specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention' has not been at all diminished by the addition of the third paragraph; the latter paragraph must be read in the light of the first and second paragraphs and given an interpretation consistent with their clear meaning. In re Arbeit [et al]. * * *" [206 F.2d 947, 41 CCPA 719].

Section 112 expressly requires that claims particularly point out and distinctly claim the subject matter of the invention. Appellant has done that in his allowed claims. But the language "an effective amount of aspirin for growth stimulation" clearly covers more than what appellant has in fact invented. To allow a claim of such vagueness and breadth would necessarily preclude others from further development in this field, else risk infringement, and would grant appellant an unjustifiable monopoly.

I would affirm.

50 CCPA

Application of Charles T. FUETTERER.

Patent Appeal No. 6897.

United States Court of Customs and Patent Appeals.

June 28, 1963.

Proceeding upon application for patent relating to tire treads and rubber stock therefor. The Patent Office Board of Appeals affirmed rejection of claims 38–49 in application serial number 498,089, and the applicant appealed. The Court of Customs and Patent Appeals held that the claims had been improperly rejected as being too ambiguous, broad and functional.

Reversed.

Worley, C. J., and Almond, J., dissented.

Patents ⇦101(6, 8)

Claims of application for patent relating to tire treads and rubber stock therefor were improperly rejected as being too ambiguous, broad, and functional. 35 U.S.C.A. § 112.

John Mahoney, Cleveland, Ohio (J. Harold Kilcoyne, Washington, D. C., of counsel), for appellant.

Clarence W. Moore, Washington, D. C. (Jack E. Armore, Washington, D. C., of counsel), for the Commissioner of Patents.

Before WORLEY, Chief Judge, and RICH, MARTIN, SMITH and ALMOND, Associate Judges.

RICH, Judge.

This appeal is from the decision of the Patent Office Board of Appeals affirming the rejection of claims 38–49 in application Ser. No. 498,089, entitled "Tire Treads and Rubber Stock Therefor." The claims stand rejected solely as "failing to define the alleged invention properly." More specifically, claims 38, 40, 42, 44, 46, and 48 have been rejected as "indefinite and ambiguous" and all claims as "unduly broad and functional."

Appellant's invention relates to a tread stock usable, for example, in vehicle tire treads which are alleged to "improve the traction of * * * tires when they engage a road or pavement which is wet or which is wholly or partly covered with a water-containing substance, such as snow or ice."

Appellant describes his invention as follows:

> "In accordance with the present invention, a carbohydrate, a protein, or mixture thereof, which is insoluble or which is only slightly soluble in cold water but which forms a colloidal suspension therein, together with one or more inorganic salts which are effective in maintaining the carbohydrate, protein, or mixture thereof, in colloidal suspension in the film of water which forms around the tire tread when the tire engages a wet or icy road or pavement,[1] are incorporated in a finely divided state in rubber, together with the other compounding ingredients which have previously been utilized in combination with rubber, to form the rubber stock for forming the tire tread.[2] "

Claim 38 is representative and reads as follows:

> "38. A rubber stock for producing tire treads including as the base portion a major proportion of rubber, a sufficient amount of a vulcanizing agent to vulcanize the rubber, and a reinforcing agent in an amount sufficient to provide a tread stock having high abrasive resistance, said rubber stock also including in addition to the base portion a mixture of a nonadhesive protein and a carbohydrate[3] which mixture is substantially insoluble in cold water and which is homogenously [sic] distributed throughout the base portion of the rubber stock, said mixture of carbohydrate and protein being approximately of a particle size that is fine enough to pass through a 300 mesh screen and being present in an effective amount ranging from more than incidental[4]

1. Appellant discloses what "inorganic salts" are suitable in the following manner:
> "I also add to the rubber stock one or more inorganic salts which are effective in maintaining the carbohydrate, the protein, or mixture thereof, in colloidal suspension in the film of water which surrounds the tire when it engages a wet or icy road or pavement. For this purpose, I may utilize a sodium salt, such as sodium carbonate, tricalcium phosphate, magnesium carbonate, or calcium carbonate."

2. The operation of appellant's tire stock to achieve its intended purpose is described as follows:
> "* * * slipping or skidding of the tire will * * * produce wear upon the tire and a small amount of the carbohydrate or protein, or a mixture thereof, will form a colloidal suspension in the film of water and will be maintained in colloidal suspension therein by the inorganic salt which is present, thereby reducing the lubricating properties of the film of water to thus provide good traction between the tire and the road or pavement on which it is being driven."

3. Reference to the use of (1) a protein *and* a carbohydrate is made in claims 38, 39, 44, and 45; (2) only a carbohydrate in claims 40, 41, 46, and 47; and (3) only a protein in claims 42, 43, 48, and 49. We disregard these differences in the claims inasmuch as appellant has not attached any significance thereto.

4. Claims 38, 40, 42, 44, 46, and 48 designate the lower limit of the added carbo-

impurities up to 20% by weight of the base portion of the rubber stock, and an inorganic salt that is capable of holding a mixture of said carbohydrate and protein in colloidal suspension in water, said inorganic salt being in a sufficiently finely divided state to form a homogenous [sic] mixture with the base portion of the rubber stock and being homogenously [sic] distributed throughout the base portion of the rubber stock and being present in an effective amount ranging from more than incidental [5] impurities up to 20% by weight of the base portion of the rubber stock and in an amount sufficient to hold the mixture of carbohydrate and protein in colloidal suspension in a film of water which forms around a tire tread composed of the stock when the tread rotatably engages a wet or icy road or pavement and small particles of the base portion of the rubber stock and small particles of the carbohydrate, protein, and the inorganic salt are worn from the tread."

The Definiteness of the Claims

The rejection of claims 38, 40, 42, 44, 46, and 48 as indefinite and ambiguous was set forth by the examiner in his answer as follows:

"The recitation 'present in an effective amount ranging from more than incidental impurities,' limiting the amount of salt, protein and/or carbohydrate present is indefinite and ambiguous since it is neither apparent how much constitutes an effective amount nor is it obvious what constitutes an incidental impurity."

The board, while ostensibly affirming this rejection, noted that the portion of the claims quoted by the examiner did not make the tire tread stock recited therein distinguishable from that disclosed by Davis et al.,[6] a reference considered by the examiner to be inapposite to the claims now before us.

After considering the Davis et al. disclosure in detail, we are unable to see its pertinence to the claims in their present form. This conclusion finds support in the failure of the solicitor to do more than note the existence of the Davis et al. reference and mention in a cursory fashion the manner in which the board made use of it in "affirming" the examiner.

The essence of the Patent Office rejection on indefiniteness is that a recitation in the *claims* of "an effective amount ranging from more than incidental impurities" would place an "undue burden * * * upon the public, to determine the operable proportions."

We think the examiner's rejection of the instant claims as failing to *enable* the public "to determine operable proportions" is misplaced. Such is the function of the *invention description* and not that of the claims.[7] Appellant stated before

hydrate and/or protein as being of "more than incidental" amount—claims 39, 41, 43, 45, 47, and 49 set this lower limit at 5% by weight of the rubber tread stock. Because of the 5% limitation in the latter claims, only the former have been rejected as indefinite and ambiguous.

5. See note 4, supra.

6. Davis et al., "Chemistry and Technology of Rubber", published by Reinhold Publishing Corporation, 1937, pages 18, 20, 26, 27 and 53. The examiner's reliance on Davis et al., a reference newly cited in his answer, was based on the premise that claims which "merely recite a stock which includes rubber, a protein and/or a carbohydrate, and an inorganic salt while the specification, at pages 7 and 8, teaches that the alleged invention lies in adding the protein and/or carbohydrate and the inorganic salt to a rubber stock" do not distinguish over "natural rubber." Appellant thereupon amended the instant claims to state that the nonadhesive protein and/or carbohydrate in his tire tread stock were "in addition to" such substances which might occur in "the base portion" of the stock. The examiner, thereupon, considered as "overcome" that portion of his answer which relied on Davis et al.

7. If support need be cited for this, see Robinson on Patents, Vol. II, particularly at § 483 (pp. 72–73) and § 504 (pp. 110–111). Also, 35 U.S.C. § 112 clearly indicates, in its *first* paragraph, that it is

the board that when "any amount of the non-adhesive protein, carbohydrate, or a mixture thereof, is present, some effect will be obtained." The Patent Office does not dispute this statement. As in the case of In re Gay, 309 F.2d 769, 50 CCPA 725, when we consider what appellant's invention really is, we find that appellant has clearly stated *in the written description of his invention* that a particular aspect thereof is not crucial, in this instance that one could vary within wide limits the amounts of non-adhesive protein and/or carbohydrate and still achieve an operable form of his invention. We do not consider pertinent to the instant rejection, which is not based on prior art, the obvious fact that if extremely small quantities of carbohydrate and/or non-adhesive protein were used the "effect * * * obtained" would be extremely small. Accordingly, insofar as the instant rejection on indefiniteness and ambiguity may be considered to be based on the failure of appellant to comply with the requirements of the *first* paragraph of 35 U.S.C. § 112, we are not persuaded that any "undue burden" is placed on the public by appellant's disclosure. We therefore reverse the rejection of claims 38, 40, 42, 44, 46, and 48 as indefinite and ambiguous.

The Undue Breadth and Functionality of the Claims

This rejection was set forth by the examiner in his answer as follows (emphasis ours):

> "The recitation 'inorganic salt that is capable of holding a mixture of said protein and/or carbohydrate in colloidal suspension' is unduly broad and functional. 'Inorganic salt' reads on literally thousands of materials, many of which would *not be operative* for applicant's purpose. For example, some salts *could* readily react with the other ingredients in the composition while other salts *could* be corrosive or destructive of the rubber. This recitation is functional since it merely describes how the salt functions as the surface of the tire wears away. It is well established that claims should set out what the materials are and not by what they do. In re Fullam 1947 C.D. 352 [34 CCPA 1018, 161 F.2d 247, 73 USPQ 399]."

The board affirmed this portion of the examiner's rejection, stating:

> "While the Examiner has not specifically listed any salt as being inoperative, his rejection is not based upon the ground of inoperativeness *per se* but rather upon the inordinate breadth of the claimed salts when it is not apparent from the disclosure of only four salts what other salts would be suitable to serve the function asserted and required by the claims."

(a) Functionality

"Functional" language in claims is not expressly condemned by the patent statutes. On the contrary, the only portion of Title 35, U.S.C., which makes any reference to the use of statements of function specifically authorizes such use.[8] If

the function of the "written description" of the invention to "enable" one skilled in the pertinent art to "make and use" the invention, and, in its *second* paragraph, that the claims have a separate and distinctive function, namely, particularly to point out and distinctly claim what "applicant regards as his invention."

Both the invention description and the claims form parts of a patent application's "specification." 35 U.S.C. § 112. However, inasmuch as the remainder of this opinion deals to some extent with the problem of analyzing the relationship that exists between the invention description and the claims, the word "specification" will not be used.

8. The third paragraph of 35 U.S.C. § 112 reads:

> "*An element* in a claim *for a combination* may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." [Emphasis ours.]

we are to affirm the Patent Office rejection based on "functionality," therefore, we must do so on the basis that (1) the type of "functionality" involved here is neither comprehended nor authorized by the third paragraph of 35 U.S.C. § 112 *and* (2) there exists a body of extra-statutory case law which specifically condemns the type of "functionality" involved in the instant claims.[9]

The board stated, as previously noted, that "Since the alleged novelty appears to reside in the result desired to be obtained by the salts, it is not proper to define the salt by what it is supposed to do rather than what it does."[10]

The sole cited support for the board's position was the Fullam case, supra, a 1947 decision of this court which we feel involved a phase of the "functionality" question which is inapposite to the instant case.

In the Fullam case, this court stated that some claims were properly rejected as "functional in claiming merely the desired result well known to and sought after by workers skilled in the art." Claims directed *merely* to a "desired result" have long been considered objectionable primarily because they cover any means which anyone may ever discover of producing the result. See, e. g., O'Reilly v. Morse, 15 How. 62, 14 L.Ed. 601; Heidbrink v. McKesson, 290 F. 665.

The desired result of appellant's invention is limiting the skidding of a tire tread stock on a wet surface. Appellant, in the claims before us, is not claiming this result. A myriad of alternative means for achieving this result can be easily thought of which would not require the particular combination of substances claimed by appellant. Insofar, therefore, as a "functional" claim may mean one which covers all means of arriving at the desired result, although the means by which such result is obtained is entirely different from that disclosed by the applicant, it is apparent that appellant's claims are not "functional."

This court in the Fullam case affirmed the rejection of certain other method claims on the basis that a polishing material recited therein was defined "not in terms of *what it is*, but of what it does. [Emphasis ours.]" This court cited General Electric Co. v. Wabash Appliance Corp. et al., 304 U.S. 364, 58 S.Ct. 899, 82 L.Ed. 1402, to support this proposition.

It was in the Wabash case that the Supreme Court condemned the use of "conveniently functional language at the exact point of novelty." The "exact point of novelty" in the Wabash case resided in statements in the claims which "distinguished [the large grained tungsten filament there involved] from the old art solely by its tendency to remedy the problems in the art met by the patent." Aside from such statements, the Supreme Court specifically held that the claims "aptly * * * describe the product of earlier manufacture."

In the instant case appellant's "exact point of novelty" is a *new combination*

9. One of the primary problems we have in coming to grips with the instant rejection is in what sense the word "functional" is being used. Few words in patent law have acquired more diverse meanings than the word "functional." Ellis, for example, in his "Patent Claims" (1949) at §§ 255–276 discusses at least five. It is for this reason that bandying about and lifting out of context statements referring to "functional" expressions, has, as Ellis euphemistically puts it, "caused confusion." In addition to Ellis, supra, some of the more recent texts which outline the confusion that exists in the case law with regard to what are "functional" statements, and how they should be treated, are:
Glascock and Stringham, Patent Law, pp. 315–324 (1943) Hoar, Patent Tactics and Law, pp. 116–118 (3rd ed., 1950) Stringham, Patent Claim Drafting, pp. 215–243 (1952) Deller's Walker on Patents, particularly at § 168 (as supplemented to 1962).

10. This statement, if correct, would lead appellant into somewhat of an impasse—statements indicating what an entity is "supposed to do" *as well as* statements indicating what that entity "does" may *both* be "functional."

of substances constituting a rubber tire tread stock. This combination is distinguishable "from the old art" in that, inter alia, it is new, i. e., no evidence exists that it describes a "product of earlier manufacture." The tendency of appellant's combination to remedy the tire skidding problems in the art is not even mentioned in the appealed claims.

It is true that appellant's inorganic salt *is* defined in terms of "what it does" rather than "what it is." We note, however, that the Supreme Court, in a seldom quoted passage in the Wabash case, stated:

> "A limited use of terms of effect or result, which accurately define the essential qualities of a product to one skilled in the art, may in some instances be permissible and even desirable * * *."

Appellant in the instant case has made just such a use of terms of result to define an essential quality of his inorganic salts.

Having carefully reconsidered the Wabash case and others, we are unable to agree with the Patent Office Solicitor that the third paragraph of 35 U.S.C. § 112 is necessarily "in derogation of the previous case law" and therefore "must be strictly construed." [11]

Furthermore, we are also unable to agree with the solicitor when he states that "the last paragraph of 35 U.S.C. § 112 is by its very language limited to claimed combinations involving mechanical structures or apparatus and methods." The word "combination" in this paragraph includes "not only a combination of mechanical elements, but also a combination of substances in a composition claim, or steps in a process claim." P. J. Federico, Commentary on the New Patent Act, 35 U.S.C.A. Vol. 1, p. 25 (1954). We agree with that statement in the commentary, which is fully supported by the legislative history.

We find particularly appropriate at this point the following words of an eight-man Patent Office Board of Appeals in Ex parte Ball and Hair, 99 USPQ 146, 148:

> "* * * the language of [the third paragraph of] Section 112 is thought to be so clear as not to require any resort to extrinsic evidence in connection with its interpretation."

The board also noted (at p. 148) that:

> "* * * some measure of greater liberality in the use of functional expressions in the definition of ele-

11. We do not mean to imply that 35 U.S.C. § 112 was not in derogation of the result reached in *any* case decided prior to the enactment of the 1952 Patent Act. See, e. g., Halliburton Oil Well Cementing Co. v. Walker et al., 329 U.S. 1, 67 S.Ct. 6, 91 L.Ed. 3. We feel, however, that a considerable body of case law, if not the preponderance thereof, before the Halliburton case interpreted broad statements of structure, e. g., "means," plus a statement of function in the manner now sanctioned by the statute. See, e. g., Westinghouse v. Boyden Power Brake Co., 170 U.S. 537, 558, 18 S.Ct. 707, 42 L.Ed. 1136. See also in this regard the February 1952 issue of the American Patent Law Association Bulletin wherein is reprinted at pp. 40–50 an address by the Hon. Joseph R. Bryson, Representative from South Carolina, given on January 24, 1952, to the Philadelphia Patent Law Association. Representative Bryson was at this time Chairman of Subcommittee No. 3 of the Judiciary Committee of the House of Representatives, which subcommittee was in charge of the legislation which resulted in the Patent Act of 1952. He stated in part (at pp. 45–46):

> "I should like to say a word on the provision in the bill for functional claiming. [H.R. 3760, 82d Cong., 1st Sess., § 112 (1951)] * * *. This provision in reality will give statutory sanction to combination claiming as it was understood before the Halliburton decision. *All the elements of a combination now will be able to be claimed in terms of what they do as well as in terms of what they are.*" [Emphasis ours.]

For a more complete analysis of the cases under the third paragraph of 35 U.S.C. § 112 since its enactment, see Woodcock, "Patent Act of 1952—Ten Years of Interpretation: Section 112," p. 157, American Bar Association Section of Patent, Trademark and Copyright Law, Summary of Proceedings at San Francisco, California (1962).

ments in proper combination claims is authorized by Section 112, than has been permitted by some of the stricter decisions of the courts in the past."

Inasmuch as it is our opinion (1) that there is no statutory ban on the use of the "functional" language employed in the instant claims by appellant; (2) that cases cited in support of the Patent Office's condemnation of the statements of function used in the instant claims are inapplicable to the situation here; (3) that the use of such functional statements as here appear is specifically sanctioned by the third paragraph of 35 U.S.C. § 112; and (4) that no objection has been made to the sufficiency of appellant's invention description to support in nonfunctional terms the functional statements made in the claims, we reverse the rejection of the instant claims as functional.

(b) *Undue Breadth*

The rejection of the claims for "undue breadth" places particular emphasis on (1) an alleged "undue burden upon the public *to determine* what salts are *suitable* for obtaining the desired results" (emphasis ours), and (2) an alleged "undue [amount of] experimentation" required of those skilled in the art to determine those salts possessing the "function asserted" by the instant claims. The undue breadth rejection phase of the instant case appears in the following posture. Appellant has *described* his invention as *comprehending* the use therein of *any* inorganic salt *capable* of performing a *specific* function in a specific combination and he has disclosed specifically four such salts which are capable of performing this function. The examiner and the board, believing that not all inorganic salts are capable of performing this function and that one skilled in the art would not know offhand which inorganic salts are capable of so functioning, have rejected the claims as "unduly broad."

It is clear that the instant claims do not comprehend a class of inorganic salts of any greater breadth than is *comprehended* by the invention description.[12] It is equally clear from this description and appellant's brief that, in the words of the *second* paragraph of section 112, "applicant regards as his invention" the combination with his other tread ingredients of *any* inorganic salt *capable* of "maintaining the carbohydrate, the protein, or mixture thereof, in colloidal suspension * * *." It is exactly this combination which appellant has particularly pointed out and distinctly *claimed* in compliance with the *second* paragraph of section 112. If, therefore, as the examiner alleges, many an "inorganic salt * * * would not be operative for appellant's purpose," this criticism bears only on the sufficiency of the invention description. But its adequacy under the *first* paragraph of section 112 has not been questioned.

We find the arguments of the board and the examiner relating to experimentation necessary to determine the suitability of *undisclosed* salts to operate in appellant's claimed combination beside the point. Appellant's invention is the *combination* claimed and not the discovery that certain inorganic salts have colloid suspending properties. We see nothing in patent law which requires appellant to discover which of all those salts have such properties and which will function properly in his combination. The invention description clearly indicates that any inorganic salt which has such properties is usable in his combination. If others in the future discover what inorganic salts additional to those enumerated do have such properties, it is clear appellant will have no control over them per se, and equally clear his claims should not be so restricted that they can be avoided merely by using some inorganic salt not named by appellant in his disclosure. The only "undue burden" which is apparent to us in the instant case is that which the Patent Office has attempted to place on

12. See note 1, supra.

the appellant. The Patent Office would require him to do research on the "literally thousands" of inorganic salts and determine which of these are suitable for incorporation into his claimed combination, apparently forgetting that he has not invented, and is not claiming, colloid suspending agents but tire tread stock composed of a combination of rubber and other ingredients.

We are not persuaded that our conclusion on this point is wrong by decisions of this and other courts relating to the sufficiency of invention disclosures in cases wherein the applicant is claiming chemical *compounds* per se.

The Patent Office rejections of claims 38–49 are reversed.

Reversed.

MARTIN, J., concurs in result only.

WORLEY, Chief Judge, with whom ALMOND, J., joins (dissenting).

I am unable to agree that the board erred in rejecting the claims on the grounds of functionality and undue breadth.

Appellant defines one of the materials in his composition as "*an inorganic salt* that is *capable of holding a mixture* of said carbohydrate and protein *in colloidal suspension* in water." (Italics supplied.) The examiner held that language failed to properly define the invention.

In affirming, the board stated:

"* * * *There is no indication that the function asserted for the salts is known in the art so that the suitable salts could be readily* determined without undue experimentation *nor is there any criteria given in the disclosure by which it could be fairly readily determined what salts are suitable.* It seems that *the determination of suitable salts thus would require testing by trial and error many thousands of known salts to ascertain those which would function in the manner required by the claims,* and such a burden should not be required of the public or even by those skilled in the art. Accordingly, we will sustain this rejection." (Italics supplied.)

I find no evidence in the record before us which would in anywise refute that reasoning and conclusion.

The basis for rejection here is clearly 35 U.S.C. § 112 which requires an applicant to particularly point out and distinctly claim his alleged invention. The issue of failure to comply with that section because of functionality introduces an element of degree, which, much like the question of obviousness, is dependent on the particular facts in each case.

It seems to me that one skilled in this art would be unable to determine, without elaborate experimentation, which salts, other than the four disclosed, are capable of performing the desired function. That is so because appellant has failed to disclose any factual criteria or scientific principles upon which equivalence can be based.

Only four examples are given in the specification and they belong to a narrow group, viz, alkaline earth or alkali salts of carbonic or phosphoric acid. The disclosure does not teach whether *any* inorganic salts, other than the four disclosed, would perform the same function. The common properties of the salts relied on to perform said function are *not* disclosed, nor are the examples sufficiently numerous to make clear what those properties might be. Since equivalent salts cannot be determined from the teaching of the disclosure or the skill of the art, surely appellant is not entitled to claim them. Discovery of suitable salts would seem to require not merely determining whether they would keep the protein and carbohydrate in colloidal suspension in a laboratory test tube, but whether they would actually maintain the suspension under conditions of use, i. e., in icy water, under the pressure of a rotating automobile tire, and for a sufficient length of time.

The claims employ functional terminology which clearly results in their being vague, indefinite and too broad. As such their allowance is precluded by 35 U.S.C. § 112. I would affirm.